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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,731	02/05/2004	Natan Bauman	NHS-0010	8615

23413 7590 12/18/2006

CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002

EXAMINER	
BRINEY III, WALTER F	
ART UNIT	PAPER NUMBER
2615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,731	BAUMAN, NATAN	
	Examiner	Art Unit	
	Walter F. Briney III	2615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,19,21-24,26-29,35-38,40 and 42-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19,21-24,26-29,35-38,40 and 42-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.**

Claims 10-12 contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims each recite that the maximum lateral dimension of the receiver is less than twenty percent of the maximum lateral dimension of the user's ear canal. Besides the fact that this is indefinite since the basis of comparison, i.e. a maximum lateral dimension of a user's ear canal, is variable since everyone has a different maximum lateral canal dimension, making an assumption of 10mm as the average largest size, means the receiver must be 2mm or less at its maximum lateral point. Considering the applicant's specification neither suggests where to purchase such a receiver or how to make such a receiver, it is up to the skill of an ordinary practitioner and the knowledge in the prior art to make such a receiver.

Unfortunately, the prior art illustrates that the smallest audio receiver obtainable at the time of the invention was larger than 2mm. For example, Knowles Electronics, which is a leader in hearing aid receiver design, produces the world's smallest armature receiver as the FK series receiver, with a maximum dimension of 2.73mm. See Knowles product catalog description for FK receiver. The size of the FK series receiver was decreased by 0.005 inches in the manner shown in US Patent 5,960,093. This minor improvement shows that those of ordinary skill in the art struggle to even find tiny ways to shrink their receivers. In addition, US Patent 6,804,368 to Tsuda of Ferrotec Corporation discloses micro-speakers with a diameter of 7.9mm. See column 4, lines 15-29. Moreover, Tsuda discloses the inherent difficulty in manufacturing micro-speakers, such as low yields, which illustrates that decreasing size causes unpredictable results and is not necessarily within the ability of one of ordinary skill in the art. See column 2, lines 38-50. In this way, it is apparent that creating a receiver dimensioned as claimed would require either innovative processes or the development of novel speaker technologies.

Evidence that unreasonable experimentation would be required is that since 1999, the lateral dimensions of the FK series receiver have remained the same, suggesting that no ordinary "tweaks" are being discovered. Second, technologies such as MEMS, which might be capable of meeting the claimed dimensions, have not even been fully developed as of July 2006, which is years away from the filing date of this application. See the article entitled "Heading to the Beginning" taken from the online journal Hearing Products Report. Therefore, as the applicant provides no direction and

no working examples for the claimed invention and as the prior art does not provide the required solution, evidence that it would have been in ability of one of ordinary skill in the art, that shrinking is a predictable exercise, or a suggestion that only minor experimentation would have been needed the above noted claims are rejected for failing to comply with the enablement requirement.

2. **Claims 1-12, 19, 21-24, 26-29, 35, 40 and 42-55, 58-60, 62, 64 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 1-12, 19, 21-24, 26-29, 35, 40 and 42-55, 58-60, 62, 64 and 66 all recite that the hearing aid claimed therein comprises a receiver generating about three decibels or below of insertion loss over a portion of the human ear audible frequencies. On page 11, lines 1-5, the applicant sets forth that two measurements were made comparing the claimed invention to competing devices. The first measurement, referred to as the Insertion Effect is defined as the difference of the real ear unaided response (REUR) and the real ear aided response (REAR). In the hearing aid art, this is referred to as real ear insertion gain (REIG). In paragraph 40 of the specification, however, the applicant appears to conflate the so-called Insertion Effect (REIG) with the term Insertion Loss, referred to as real ear occluded gain (REOG). This confusion renders all claims referring to insertion loss indefinite. For the purposes of this action, insertion loss will be interpreted as REIG since it appears to have been what was actually measured by the applicant.

Moreover, not even clarifying this matter would resolve the indefiniteness of the claims since all controls of the test must be disclosed in order for the Office to make a sound judgment on patentability. For example, in measuring real ear response, it is critical that stimulating sound input levels are reported, since the ear may non-linearly amplify/attenuate sounds.

Claims 8-12, 36-38, 56, 57, 61, 63, 65 and 67 all recite that a maximum lateral dimension of the receiver is less than a certain percent of the maximum lateral dimension of a user's ear canal. This limitation is a relative measure as it compares the lateral dimension of a first element to the lateral dimension of a second element. Because the dimension of the second element is variable and because the first element is quantitatively sized relative to the second element, it follows that the lateral dimension of the first element is indefinite. See MPEP 2173.05(b) and Ex parte Brummer, 12 USPQ2d 1653, where a claim was made to a bicycle (hearing aid) that recited "said front and rear wheels so spaced as to give a wheelbase (maximum lateral dimension of a receiver) that is between 58 percent and 75 percent of the height (maximum lateral dimension of a user's ear canal) of the rider (user) that the bicycle was designed for." For purposes of this Office Action, a generous value of 10mm will be used as an average maximum lateral dimension of a user's ear canal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-7, 40, 42-53 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage et al. (US Patent 5,987,146).**

Claim 1 is limited to "a hearing aid." Likewise Pluvinage teaches a hearing aid, in particular, an open ear canal hearing aid system with the speaker in the ear canal as disclosed in the Abstract. The embodiment of most importance herein is depicted in figure 7. Therein, the hearing aid is shown to comprise a "speaker" 44. The speaker is held in place by one of the ear tips shown in figures 3a, 3c, 4a and 4c. Figures 4a and 4c illustrate ear tips including flanges 21 for suspending the tube 30 within the ear canal as well as the speaker 44 mounted at the end of the tube. See column 5, lines 31-55. As seen in figure 7, sound received at microphone 42 is processed in accordance with hearing loss programming within processor 48 and passed via an electrical connection within tube 30 to speaker 44. As seen in figure 5a, tube 30 passes over the external ear and through the ear canal opening. Since the signals output by the processor are electrical tube 30 must comprise an electrical connection to electroacoustic transducer 44. Moreover, processor 48 corresponds to an amplifier 48 and is clearly positioned within the behind the ear unit.

Concerning the claim that the receiver generates three decibels or below of insertion loss over a portion of the human ear audible frequencies, it was shown above that this limitation attempts to define the structure of a hearing aid receiver based on its function. Unfortunately, the function is incomplete in its description to the point that the

structure of the receiver is indefinite. Because of things like non-linear varying unoccluded responses of ears and variability of the stimulus, the test result of 3 dB is next to meaningless in defining the structure of the claimed invention. For example, inputs of varying intensity comprising the same frequency content will potentially produce varying amounts of insertion loss. Moreover, the conflation of terms leads to indefiniteness. However, for the purposes of this Office Action, it will be assumed that both the applicant and Pluvinage measured insertion loss in the same manner.

Pluvinage depicts in figure 11 the insertion gain in dB provided by the invention over a wide range of input frequencies. While insertion gain takes into account electronic amplification, it is noted that for an input of 80 dB SPL, near 0dB of amplification is provided. See column 8, lines 15-25. In this way, the measurements for an 80 dB SPL input should mimic only the insertion loss generated by inserting the speaker arrangement of Pluvinage in a user's ear. As seen in figure 11, there are no areas for an 80 dB SPL input that show more than 3 dB of loss. Although figure 11 indicates that for an input of 80 dB SPL the insertion loss is actually positive, this can be attributed to resonance generated by inserting the speaker into the ear.

Although Pluvinage discloses a device significantly similar to what is claimed, it cannot be shown that Pluvinage anticipates the claimed invention. Specifically, Pluvinage fails to place the microphone sampling position outside of the ear canal. However, this deficiency is overcome by an obvious modification.

Concerning the microphone sampling position, Pluvinage remarks that sampling behind the ear can degrade sound quality. See column 2, lines 51-56. Despite this

evidence of teaching away, it is noted that merely eliminating an element and its function is obvious if the function of the element is not desired. See Ex parte Wu, 10 USPQ 2031; In re Larson, 144 USPQ 347; and In re Kuhle, 188 USPQ 7. In this way, removing the tube 32 connecting microphone 42 to the ear canal and thus eliminating the function of sampling within the ear canal would have been obvious provided the sampling function was not desired. It is reasonable that because the Pluvinage patent provides protection for a hearing aid with said sampling position, eliminating said canal sampling position and reverting to the known external sampling position would have been desirable for avoiding direct copying and potential infringement of Pluvinage's patent. Not only this, but the tube 32 clearly presents an acoustic mass, which will modify any sound input thereto. So while it may allow sampling within an ear canal, taking advantage of the user's outer ear frequency response, it also creates acoustic noise. This analysis illustrates that Pluvinage's disclosure may solve some problems of the claimed invention, however, Pluvinage's solution creates more problems, defining an area of design choice/tradeoff that weakens any allegation that Pluvinage teaches away to a degree rendering the proposed modification nonobvious.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to remove the sound tube 32 of Pluvinage since mere elimination of an element and its function is obvious provided that the function is undesired, which it certainly is in this case. Although some problems are solved, the solution creates extra problems that are not necessarily less burdensome or troubling. Furthermore,

eliminating the tube 32 allows a practitioner the ability to take advantage of open ear receiver hearing aids without licensing Pluvinage's invention.

Claims 2-6 and 42-53 are limited to "the hearing aid according to claim 1," as covered by Pluvinage. Each of these claims recites a particular insertion loss over a particular frequency range. It is respectfully submitted that based on the assumptions apropos the rejection of claim 1, figure 11 of Pluvinage provides a reasonable disclosure of the insertion loss of Pluvinage's hearing aid. As seen in figure 11, all recited insertion losses are disclosed. Therefore, Pluvinage makes obvious all limitations of the claims.

Claim 7 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. The claim recites that the receiver is in either the bony region, the cartilaginous region or both. These three positions are all the possible locations for a receiver in the ear canal, so Pluvinage must disclose this. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 40 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. As seen in figure 1, a stiffening member 14 is provided in addition to an intermediate connection portion 10 and an electrical conducting component that is not shown but is inherent based on the disclosure that a speaker is placed in the ear canal. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 59 is limited to "the hearing aid according to claim 40," as covered by Pluvinage. Pluvinage illustrates element 14 as a wire. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 60 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. As seen in figure 10, the hearing aid of Pluvinage is envisioned to include programmable circuitry, under control of control circuitry 80. The circuitry and program memory is encased in the BTE unit 40. See column 6, lines 46-67. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 62 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. Column 7, lines 6-16, describes that the control circuit controls the compressors, rendering the compressors "reprogrammable." Therefore, Pluvinage makes obvious all limitations of the claim.

Claims 61 and 63 recite essentially the same limitations as claims 60 and 62, and are rejected for the same reasons.

4. **Claims 8, 26-29, 35-37 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog.**

Claim 8 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. Pluvinage discloses that his receiver is an EH series receiver by Knowles Electronics. This receiver is known to have a maximum lateral dimension of 3.55mm. See Knowles Product Catalog description of the EH series receiver. Assuming that an average human's ear canal has a maximum lateral opening of 10mm at the entrance to the canal, it is seen that the disclosed EH series receiver is "less than half a maximum lateral dimension of a user's ear canal." Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 26 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. Speaker 44 of Pluvinage is actually a Knowles electronic receiver. These receivers include an internal speaker as well as a metallic casing as claimed. As specified by Pluvinage an EH series receiver is used, which inherently includes first and second end portions as seen in the Knowles online product catalog. The two terminals of the receiver are located on a first end different than the second end, and must communicate with the intermediate connection portion 30 connecting the speaker to the electrical output of sound processor 48. On the other end is a port clearly seen in the product catalog's EH series receiver image. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 27 is limited to "the hearing aid according to claim 26," as covered by Pluvinage. As seen in figure 4b of Pluvinage, an ear tip 12 is provided in communication with the speaker's 44 port. This tip includes a membrane 18b that protects the port from debris. See column 5, lines 31-55. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 28 is limited to "the hearing aid according to claim 27," as covered by Pluvinage. The solid construction of the EH series receiver seen in the product catalog clearly seals the casing to debris at the first end portion and along a length of the casing extending to the port. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 29 is limited to "the hearing aid according to claim 26," as covered by Pluvinage. As seen in figure 4b of Pluvinage, an ear tip 12 is provided in communication with the speaker's 44 port. This tip includes a membrane 18b that

protects the port from debris, including cerumen. The tip is also removable. See column 5, lines 31-55. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 35 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. The Knowles EH series receiver includes at least two ports, so that at least two electrical conducting components must be routed through intermediate connecting portion 30 to the speaker. See Knowles Product Catalog description of EH series receiver. Since electrical conductors cannot bridge each other, it is inherent that they must be isolated for proper operation. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 54 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. This claim seeks to limit the structure of the claimed hearing aid based on how it is employed. In this way, it is only necessary that the hearing aid be dimensioned such that the receiver could conceivably be positioned within the cartilaginous outer region of the ear canal of the user. This is clearly possible with the hearing aid of Pluvinage since the receiver is only 3.55mm in maximum lateral dimension versus, where the maximum lateral entrance to an ear canal is about 10mm. Therefore, Pluvinage makes obvious all limitations of the claim.

Claim 55 is limited to "the hearing aid according to claim 1," as covered by Pluvinage. As seen in figure 5b, the tube 10 is suspended within the ear canal and away from the walls, such that a receiver mounted within the tubing would also be so suspended. Figures 4a-4d provide optional tips for supporting a receiver in a canal. Therefore, Pluvinage makes obvious all limitations of the claim.

Claims 56 and 57 recite essentially the same limitations as claims 54 and 55, and are rejected for the same reasons.

Claims 36 and 37 recite essentially the same limitations as claim 8, and are rejected for the same reasons.

5. Claims 9 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog and Miller (US Patent 5,960,093).

Claim 9 is limited to "the hearing aid according to claim 8," as covered by Pluvinage. The EH series receiver disclosed by Pluvinage has a maximum lateral dimension of 3.55mm, which is greater than thirty percent of an average human's maximum lateral ear canal dimension of 10mm. However, this deficiency is overcome by an obvious modification. In particular, Pluvinage does not require the use of the EH series receiver, but merely uses it in one embodiment. Since 1997, Knowles electronics has released a plurality of smaller receivers, such as the FK series receiver, a description of which is provided in Miller (US Patent 5,960,093). This receiver has a maximum lateral dimension of 2.73mm, which is "less than thirty percent of a maximum lateral dimension of a user's ear canal." As the receivers are functionally equivalent, are both manufactured by the same company, and are both designed for use in hearing aids, it is obvious to replace one with the other.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace a known receiver by Knowles with another functionally equivalent receiver used in the field of hearing aids and that is advantageously smaller

so that it leaves the ear canal more open, which conforms to the design goals of Pluvinage.

Claim 38 recites essentially the same limitations as claim 9 and, and is rejected for the same reasons.

6. **Claims 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of Mansgold et al. (US Patent 4,425,481).**

Claims 64 and 66 are limited to "the hearing aid according to claim 1," as covered by Pluvinage. These claims refer to user selection of multiple hearing aid programs stored in the BTE. Pluvinage fails to disclose this feature, however, this deficiency is overcome by an obvious modification.

In particular, it is well established that providing multiple sound programs within a single hearing aid allows a user to choose between programs optimized for various listening situations. Such a concept is illustrated by Mansgold, who discloses a programmable signal processing device. See column 1, line 11, through column 2, line 22.

It would have been obvious to provide multiple programs in a memory within the BTE unit of Pluvinage for the purpose of allowing a user to select between optimal settings for a specific listening environment without having to change hearing aids.

Claims 65 and 67 recite essentially the same limitations as claims 64 and 66, and are rejected for the same reasons.

7. **Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley et al. (US Patent Application Publication 2004/0010181) in view of Fretz et al. (US Patent Application Publication 2003/0002700) and Pluvinage.**

Claim 1 is limited to "a hearing aid." Similarly, Feeley discloses a hearing aid as seen in figure 1. The hearing aid of Feeley includes a BTE unit 33 comprising a microphone 62 that samples outside of the canal, and a receiver 13 suspended within an ear canal of a user by way of mold 11. As seen in figure 6A, input from microphone 62 is sent to processing circuitry 61, which outputs to connector 60 and then to receiver 13 by way of connectors 20 and 31. Circuitry 61 processes microphone signals according to hearing loss programming. See paragraphs [0056] through [0057]. Since BTE unit 33 sits behind the user's cartilage, the output of the amplifier circuitry 61 is passed electrically around a portion of the user's external ear using wires 22. See paragraphs [0069] and [0072]. As seen in figure 6A, the microphone 62 and amplifier 61 are in the BTE unit 33. While Feeley discloses many elements of the claimed invention, Feeley does not disclose that the receiver is suspended in an open ear configuration since a mold is used, and that the receiver generates about three decibels or below of insertion loss over a portion of the human ear audible frequencies. However, these deficiencies are overcome by an obvious modification.

In particular, the use of ear molds, as used by Feeley, in hearing aids has been recognized in the art as problematic. Namely, Fretz discloses in paragraphs [0007] and [0008] that blocking the canal creates occlusion and reduction in natural sounds and that venting is not sufficient. Moreover, Fretz states that using molds requires either expensive fitting procedures or the use of stock canal ear tips, which are at best

uncomfortable. See paragraphs [0010] and [0011]. All these disadvantages of molds led Fretz to design an open ear canal design. See paragraphs [0002] and [0013] as well as figure 1, which illustrates a tube 12 coupled to a BTE unit 10 and a maintaining ear tip 14.

It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the mold 11 of Feeley with an open ear tip as taught by Fretz for the purpose of alleviating all the problems enumerated by Fretz, and which happen to coincide with many of the advantages purported to have been solved by applicant's invention. In fact, the only advantage not taught by Fretz is that of acoustic tube resonance, but since Feeley is the base reference being modified and does not include said resonance noise, this advantage is moot and a solid case of obviousness stands.

Regarding the claimed insertion loss, since Feeley fails to specify which receiver to use, except to say that any Knowles receiver is preferred. See paragraph [0038]. The Knowles receiver catalog provides both EH series receivers as used by Pluvinage (US Patent 5,987,146) as well as even smaller FK series receivers. Since Pluvinage used an EH series receiver and achieved insertion gain (which is assumed for the purposes of this Office Action to be what the applicant intended by the term insertion loss) in the range claimed, it is reasonable that merely picking the EH series receiver from the Knowles list would render this remaining claim limitation obvious in view of the prior art.

It would have been obvious to one of ordinary skill in the art to use the EH series receiver made by Knowles electronics in the hearing aid of Feeley since Feeley expressly suggests using any Knowles receiver.

8. **Claims 19, 21-24 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz and Pluvinage and further in view of GN Magazine from January 2005, the ReSoundAiR pamphlet from September 2003 and the GN ReSound article from April 2003.**

Claim 19 is limited to "the hearing aid according to claim 1," as covered by Feeley in view of Fretz. The hearing aid of Feeley includes an intermediate connection portion 21 containing electrical connections 22. This portion ends at a mold that suspends a receiver 13 in an ear canal of a user. However, in accordance with the rejection of claim 1, the mold is replaced with an open ear tip 14 as seen in figure 1 of Fretz. However, neither Feeley nor Fretz discloses a retaining member as claimed. This deficiency is overcome by an obvious modification.

First, it is noted that figure 1 of Fretz supports the language of Fretz's claim 1. It is also noted that figure 1 and claim 1 are embodied in the commercially available GN ReSoundAiR hearing aid, which was released in May 2003. See GN Magazine 1-05, page 13, column 1, lines 7-8. As seen on page 12 of the ReSoundAiR pamphlet released 8 September 2003, the ReSoundAiR includes a sports lock extending from the intermediate connection portion, labeled as number 12 in figure 1 of Fretz. This sports lock is disclosed as contacting the concha of the user and providing increased retention

of the ear tip within the ear canal. See GN ReSound article entitled "An Innovative Non-Occluding DSP Device" generated April 10 2003, figure 1 and page 2, column 2.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to couple a retaining sports lock to the intermediate connection member of Fretz as taught by the ReSoundAiR pamphlet and GN ReSound article for the purpose of increasing retention of the ear tip within the ear canal.

Claim 21 is limited to "the hearing aid according to claim 19," as covered by Feeley in view of Fretz and further in view of the GN Magazine, the ReSoundAiR pamphlet and the GN ReSound article. The similarity in structure between the sports lock disclosed in the pamphlet and article and the retaining member 54 seen in figure 4 of the application means that the sports lock will provide the same functionality as claimed. Therefore, the cited prior art makes obvious all limitations of the claim.

Claim 22 is limited to "the hearing aid according to claim 19," as covered by Feeley in view of Fretz and further in view of the GN Magazine, the ReSoundAiR pamphlet and the GN ReSound article. Again, the similarity in structure between the sports lock and the claimed retention member 54 as seen in filed figure 4 supports an inherency argument that the sports lock will perform the claimed function. Therefore, the cited prior art makes obvious all limitations of the claim.

Claim 23 is limited to "the hearing aid according to claim 19," as covered by Feeley in view of Fretz and further in view of the GN Magazine, the ReSoundAiR pamphlet and the GN ReSound article. As noted in the rejection of claim 19, the sports

lock acts to retain/stabilize. Therefore, the cited prior art makes obvious all limitations of the claim.

Claim 24 is limited to "the hearing aid according to claim 19," as covered by Feeley in view of Fretz and further in view of the GN Magazine, the ReSoundAiR pamphlet and the GN ReSound article. As noted in the rejection of claim 19, the sports lock acts to retain/prevent movement. Therefore, the cited prior art makes obvious all limitations of the claim.

Claim 58 is limited to "the hearing aid according to claim 19," as covered by Feeley in view of Fretz and further in view of the GN Magazine, the ReSoundAiR pamphlet and the GN ReSound article. The ReSoundAiR pamphlet and GN ReSound article clearly illustrate the sports lock as a wire. Therefore, the cited prior art makes obvious all limitations of the claim.

9. **Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz and Pluvinage and further in view of the Knowles product catalog and Miller.**

Claims 36-38 are limited to "a hearing aid." These claims are rejected in view of Feeley and Fretz for the same reasons apropos claim 1 as well as the following. It is noted that the claimed receiver's maximum lateral dimension is less than fifty/forty/thirty percent of the maximum lateral dimension of a user's ear canal. As noted in the rejection of claim 1, it would have been obvious to pick, for example, the Knowles FK series hearing aid receiver since Feeley expressly permits selection of any viable Knowles receiver. The FK series receiver's maximum lateral dimension is 2.8mm, which is less than thirty percent (3mm) of an average maximum lateral dimension of

10mm, and thus satisfies the claimed requirement. The available date of the FK series receiver is established in the Miller patent. Therefore, Feeley in view of Fretz and the Knowles product catalog makes obvious all limitations of the claims.

Response to Arguments

Applicant's arguments filed 02 November 2006 have been fully considered but they are not persuasive.

Despite the new grounds of rejection presented in this Office Action, which render the applicant's traversal of the previous rejections moot, the secondary considerations of non-obvious filed 28 November 2006, 02 November 2006 and 14 September 2006 will be treated herein since they relate to any prima facie case of obviousness.

Regarding evidence of commercial success

In the declaration by Leon Hirsch and corresponding evidence section 2, the applicant shows that Vivatone made a total of 12,332 unit sales domestically of a product embodying the invention recited in at least claim 1. In reckoning the weight of commercial success, it is noted that raw numbers are meaningless without a backdrop of market share. In fact, MPEP 716.03(a)(IV) refers to Cable Electric Products, Inc. v. Genmark, Inc., 226 USPQ 881 (Fed. Cir. 1985), to show that: "Gross sales figures do not show commercial success absent evidence as to market share... the time period during which the product was sold, or as to what sales would normally be expected in the market. It is evident based on the declaration of Leon Hirsch and appendix 2 that

very little money was spent on advertising and that Vivatone was not a "house-hold" name in the hearing aid business at the time of the invention, however, failing to provide a bigger picture of what market success really means in the hearing aid field undermines any alleged success story. Specific questions to be answered include: (1) average introduction time of a hearing aid; (2) average advertising budgets; and (3) market share.

Regarding (1), two years appears reasonable for wide dissemination of a new product, but there simply is not enough background to determine how long it takes for a hearing aid design to catch on.

Regarding (2), while some of the larger companies, i.e. Siemens, might have a large advertising budget, hearing aids are not the type of device you see advertised on TV or in popular magazines. Despite any amount of advertisement, however, a hearing aid is a medical device and as such is distributed in a controlled manner by trained prescribing technicians, such as audiologists. Much like selling blood pressure or cholesterol lowering medication, the sales of hearing aids seems reasonably contingent on familiarity of a prescribing professional (e.g. physician) more so than that of a consumer. In this way, the size of the advertising market is significantly reduced, reducing the overall cost of advertising. Furthermore, these prescribing professionals are required to earn continuing education credits in many circumstances, and therefore, stay abreast of new technologies. Ergo, technical journals and word-of-mouth (e.g. audiologist to audiologist) provides ample free advertisement.

Regarding (3), the Patent Office simply does not have the resources for gathering market data, however, the examiner found an article dated March 2000 from the website findarticles.com entitled 'Hearing Aid Sales Up a Little In '99' taken from The Hearing Journal. This article indicates that net domestic unit sales of hearing aids in the United States (the domestic venue for Vivatone) were 1,891,250. Taking the best selling year for Vivatone into account (i.e. 2005), Vivatone's sales account for 0.65% of all hearing aid sales in the United States. This definitely does not strike one as evidence of a wide market share. A second article taken from The Hearing Journal dated December 2005 and entitled "Hearing aid sales slip back to norm, but leaders see growth potential" establishes that net hearing aid sales will amount to 2,214,423 units for 2005. In this market, the Vivatone device accounted for 0.56% of all domestic hearing aid sales. Moreover, Vivatone accounted for 1.78% of all BTE units, which include mini-BTE units with open fittings. See page 14 under the section entitled "BTE Resurgence Accelerates." These numbers suggest at least 'exploratory' success where the curiosity of a consumer leads him to make a purchase rather than a "got to have it" type of success like the I-Pod experienced. In fact, the second article contains a statement on page 15 by Alan Dozier, chief operating officer of the GN ReSound Group, that, "with all the performance improvements, the question is, why do we continue to get 2%, 3% and 4% growth?" Clearly, the hearing aid market is frustrated and as Alan Dozier states, "its one thing to improve technology, but translating that to consumers so they understand the benefits is quite another matter." Mr. Dozier also characterizes the improvements to hearing aids as "incremental improvements" rather than large scale

improvements that revolutionize hearing aids, the so-called "wow" reaction. See page 20, column 2, lines 13-21. So to interpret Vivatone's sales figures as evidence of commercial success seems contrary to both Vivatone's limited market share as well as the general feeling in the art that hearing aid sales see very limited growth despite technological improvements—which are, in all reality, incremental improvements.

Incidentally, Mr. Dozier also says on page 15, "Not a lot of consumer advertising is being done to build confidence in hearing instruments and build brand awareness." This statement buttresses the examiner's earlier skepticism apropos question (2) supra.

This second article on page 14 does illustrate that the open fitting model, per se, led to an increase in BTE sales, however, this article also illustrates that mini-BTE units were prevalent during Vivatone's leading earnings year. In particular, the language "mini-BTEs...most of them using open fittings" is unambiguous in stating that many manufacturers produced open fitting hearing aids through 2005. Although this passage suggests that open fitting technology leads to commercial success, there is no mention of a receiver in the ear, only open fitting. As applicant's invention is characterized by both elements, one can only guess at the effect of adding a receiver in the ear.

Moreover, on page 20 it is noted that the open fitting approach to hearing aids was pioneered by at least one company other than Vivatone, namely GN ReSound. See page 20, column 2, lines 13-27. Unsurprisingly, the Pluvinage et al. and Fretz et al. prior art references relied on supra are both owned by ReSound and clearly point toward open fitting technology and, in addition, receiver in the ear technology. If Vivatone was truly a source for revolutionary change as alleged by the applicant's claim

of laudatory statements by competitors, it seems conspicuous that Vivatone is neither represented nor mentioned in a summary of hearing aid sales for 2005 that recognizes the contribution of mini-BTEs using open fitting technology. This, suspicion is supported by the fact that Vivatone made up only 1.78% of the total BTE sales for 2005.

If another entity/assignee was responsible for innovating a technology that another entity/assignee uses to gain commercial success, the law is quite clear that the evidence supporting the latter's commercial success is moot as the improvements and modifications relied upon were the work of another. See MPEP 716.03(b)(II). As shown above, the second retrospective article taken from December 2005 shows that ReSound had pioneered open fitting technology, which at least in part caused resurgence in BTE unit sales for 2005. The statements that ReSound pioneered such technology is supported by both the Pluvinage et al. and Fretz et al. references relied upon supra, both of which expressly point toward the use of open fittings to eliminate negative effects, such as occlusion and retaining natural amplification. See Pluvinage column 2, lines 13-34 and 59-64, and Fretz paragraphs [0007], [0008], [0010] through [0013]. Moreover, Pluvinage teaches placing a speaker in the ear while maintaining an open ear canal. See Abstract.

If somehow one maintained his position that Vivatone created a non-obvious device, the non-obvious portion clearly could not reside in the innovations of another. In this case, Pluvinage expressly invented a hearing comprising a BTE unit, a receiver in the ear, wherein the receiver is configured to leave the ear canal open. While the insertion loss of the Pluvinage's hearing aid is not discussed here (see the above

rejection(s) of claim 1), we will assume that all open ear devices attain no more than 3dB of insertion loss over at least some portion of the audible frequency range. Therefore, the only difference between claim 1 and this prior art is the microphone sampling position. Yet, none of the evidence on the record indicates that placing the sampling position external to the ear canal of the user is non-obvious.

Specifically, there is simply no evidence of commercial success being won through this process. The Oticon paper entitled "Delta Audiology Concept" discusses the use of directional microphones external to the ear canal, there is no evidence that two microphones are used in the Vivatone device to achieve similar directionality. The INTERTON Shape hearing aid advertisement lauds the separation of microphone and speaker, but only for the purpose of reducing mechanical feedback, not for eliminating acoustic feedback. However, the Pluvinage hearing aid inherently reduces mechanical coupling between the microphone and receiver as well as inductive feedback simply based on the separation of the microphone and receiver. Acoustic feedback is minimized electronically. Moreover, Pluvinage contemplates placing the microphone sampling position external to the user's ear canal, but discards it in view of various deleterious effects. See column 2, lines 51-67. If anything, the Vivatone hearing aid could be seen as a degenerate of Pluvinage's hearing aid, since the former lacks sampling within the canal, which provides "better quality sound." See column 6, lines 14-16, of Pluvinage.

In view of the foregoing, it is clear that the applicant has failed to meet his burden in establishing clear evidence of commercial success. Moreover, even if evidence to

substantiate a claim to commercial success were provided, the prior art already contemplated each of the applicant's alleged innovations, rendering the invention obvious.

Regarding evidence of copying, long felt need and laudatory statements by competitors

The evidence of copying provided by itself is hardly convincing of non-obviousness. Section 716.06 of the MPEP highlights that beyond non-obviousness, many factors contribute to copying. While the claim language reads on several hearing aid devices in the evidence appendices, it is not clear that any of the copiers were "[expending] great effort to develop [their] own solution." Moreover, the alleged copiers could have just as well been inspired by the disclosures of GN ReSound and Hear Wear—which owns the invention by Feeley et al., relied upon above. Quite possibly, ReSound's competitors may have copied the hearing aid of Pluvinage but eliminated an unnecessary component, namely the tubing between the canal and microphone, to avoid licensing.

Vivatone's competitors appear to laud the innovations of open fitting coupled with receiver in the ear, however, it has been shown that those of ordinary skill in the art knew these innovations at the time of the invention. Namely, open ear hearing aids and receivers placed in the ear were known, even in combination.

Although the applicant purports a long felt need to solve problems such as occlusion, feedback and speaker tube resonances, Pluvinage single-handedly did away with these problems in 1997, although not published as a patent until almost 2000. This

is readily apparent from the fact that Pluvinage's hearing aid comprises an open ear receiver, which on its own reduces insertion loss, occlusion and resonance. Furthermore, the separation of the microphone and speaker reduces feedback. In addition, Feeley also eliminated feedback and resonance through separation of a microphone and speaker, and fairly treated occlusion and insertion loss by designing an open-mold that fits deep in the ear. Although not comprising a receiver in the ear, express suggestion to replace molds with open ear configurations is provided in at least the Fretz reference. Placing Feeley and Fretz side-by-side inexorably leads to the marriage of an open ear to a receiver in the ear. This is shown more fully in the above rejections section.

In summary, each of the secondary considerations of non-obviousness presented by the applicant have been treated. The evidence of commercial success provided by the applicant is incomplete, and cannot be relied upon to make a conclusion of non-obviousness. In addition, the Office's own research shows that Vivatone's sales are unphenomenal in the hearing aid market. Moreover, the research indicates that advertising for hearing aids is generally small, that open ear fitting offerings from various companies were widely accepted during 2005, and that the GN ReSound group is credited with pioneering such technology.

The evidence of copying is incomplete as it fails to show why the alleged copying took place, e.g., extended effort on the part of the alleged copiers. Further, strong motivation to generate the applicant's invention comes from avoiding licensing of existing open ear receiver hearing aids from the likes of ReSound.

The evidence of laudatory statements can be directed not only to the applicant's invention but the Pluvinage and Feeley hearing aids.

The evidence of long felt need is rendered moot in view of others already resolving the alleged long felt needs. Again, both Pluvinage and Feeley address each long felt need, namely: occlusion, insertion loss, feedback and resonance effects. Therefore, the above obviousness rejections of the claimed invention are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter F. Briney III whose telephone number is 571-272-7513. The examiner can normally be reached on M-F 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sinh Tran can be reached on 571-272-7564. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

wfb

SINH TRAN
SUPERVISORY PATENT EXAMINER